

DemeMASK Surgical N95 Respirator

DT-S95001-C/DT-S95001-CS

The DemeMASK Surgical N95 Respirator is designed to help provide respiratory protection for the wearer. This respirator has a filter efficiency level of at least 95% against particulate aerosols free of oil†. It is fluid resistant‡. It is disposable and may be worn in surgery. It can fit a wide range of face sizes. This product contains no components made from natural rubber latex.

IMPORTANT

Before use, the wearer must read and understand these *User Instructions*. Keep these instructions for reference.

INTENDED USE:

This product meets CDC guidelines for M.tuberculosis exposure control. As a respirator, it is intended to help reduce wearer exposure to certain airborne particles, including those generated by electrocautery, laser surgery, and other powered medical instruments. As a surgical respirator, it is designed to be fluid resistant to splash and spatter of blood and other infectious materials‡.

CONTRAINDICATIONS:

DemeTECH recommends that this respirator is not for industrial use. Not for use with beards or other facial hair or conditions that prevent a good seal between the face and the sealing edge of the respirator. Does not protect against gases or vapors (i.e. anesthetic gases such as isoflurane or vapors from sterilants such as glutaraldehyde). This respirator was not designed to be used by children.

† Tested against a 0.3 micron particle (mass median aerodynamic diameter) per U.S. 42 CFR 84.

‡ Meets ASTM Fluid Resistance Challenge F1862 at 80 mmHg

S-SPECIAL OR CRITICAL USER INSTRUCTIONS

This respirator has been approved as a NIOSH N95 filtering facepiece respirator, for use in healthcare settings, as a Surgical N95 Respirator conforming to recognized standards for biocompatibility, flammability, and fluid resistance.

1. Before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the local government requirements. In the United States, employers must comply with OSHA 29 CFR 1910.134 which includes medical evaluation, training, and fit testing.
2. The respirator is designed for occupational/professional use by adults who are properly trained in on use and limitations. The respirator is not designed to be used by children.
3. The respirator can help protect the wearer's lungs against certain airborne contaminants; however, it will not prevent entry through other routes such as the skin or eyes, which would require additional personal protective equipment (PPE).
4. Individuals with a compromised respiratory system, such as asthma or emphysema, should consult a physician and complete a medical evaluation prior to use.
5. Respirator may be used until damaged, breathing becomes difficult, or contaminated.
6. Filtering facepieces are to be inspected prior to each use to good operating condition. Examine all the respirator parts for signs of damage including the two headbands, nose foam, nose clip and facepiece material. The respirator should be disposed of immediately upon observation of damaged or missing parts. Immediately replace respirator if damaged.
7. Discard after every use. Follow national, state, local, and facility infection control guidance and policies.

Fitting Instructions (Must be followed each time respirator is worn)

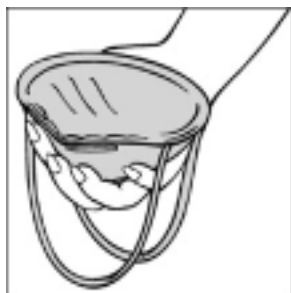


Fig. 1



Fig. 2



Fig. 3



Fig. 4

1. Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand.
2. Position the respirator under your chin with the nosepiece up. Pull the top strap over your head resting it

high at the top back of your head. Pull the bottom strap over your head and position it around the neck below the ears.

3. Place your fingertips from both hands at the top of the metal nosepiece. Using two hands, mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece



Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance. Use two hands.

4. Perform a User Seal Check prior to each wearing. To check the respirator-to-face seal, place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step 3. If air leaks at the respirator edges, work the straps back along the sides of your head. **If you CANNOT achieve proper seal, see your supervisor.**

REMOVAL INSTRUCTIONS

See step 2 of *Fitting Instructions* and cup respirator in hand to maintain position on face. Pull bottom strap over head. Still holding respirator in position, pull top strap over head and remove respirator.

This respirator is approved only in the following configuration:



DemeTECH Corporation
 14175 NW 60th Avenue
 Miami Lakes, FL 33014
 1-888-324-2447



This respirator is approved only in the following configuration:

TC-	Protection ¹	Respirator		Cautions and Limitations ²
		DT-SN95001-C	DT-SN95001-CS	
84A-9296	Surgical/N95	X	X	ABCJMNOS

1. Protection

N95 - Particulate Filter (95% filter efficiency level). Effective against particulate aerosols free of oil; time use restrictions may apply.

2. Cautions and Limitations

- A. Not for use in atmospheres containing less than 19.5% oxygen.
- B. Not for use in atmospheres immediately dangerous to life or health.
- C. Do not exceed maximum use concentrations established by regulatory standards.
- J. Failure to properly use and maintain this product could result in injury or death.
- M. All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N. Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O. Refer to User Instructions and/or maintenance manuals for information on use and maintenance of these respirators.
- S. Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

FOR MORE INFORMATION and assistance contact your local DemeTECH representative or call DemeTECH Customer Service toll free at 1-888-324-2447



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